90. The pharmaceutical dosage form of claim 85, in the form of a drink.

91. The method of claim 51, wherein the fenofibrate-responsive condition, disease or disorder is a lipid disorder.

92. The method of claim 91, wherein the lipid disorder is an above-normal level of cholesterol.

93. The method of claim 91, wherein the lipid disorder is an above-normal triglyceride level.

94. The method of claim 91, wherein the lipid disorder is a below-normal level of high density lipoproteins.--

REMARKS

INTRODUCTORY COMMENTS:

In the Office Action under reply, pending claims 1-12 and 37-51 were examined, claims 13-36 having been withdrawn as a result of restriction. The claims were rejected as follows: under 35 U.S.C. §112, second paragraph (claim 51); under 35 U.S.C. §102(b) as anticipated by Edgar et al. (claims 1-4, 37, 41-44 and 51); and under 35 U.S.C. §103(a) as obvious over Edgar et al. in view of Patel et al. (claims 5-12, 38-40 and 45-50). Claims 37-49 and 51 were also objected to as being dependent upon non-elected claims 13-36.

The foregoing objections and rejections are addressed in part by the above amendments and in part by the comments that follow. With the above amendments, claims 2, 13-36, 39, and 47-49 have been canceled, claims 1, 3, 5, 8, 10, 37-43, 50 and 51 have been amended, and new claims 52-94 have been added. Thus, claims 1, 3-12, 37, 38, 40-46 and 50-94 are now pending.

For the Examiner's convenience, the pending claims upon entry of this amendment are set forth in Appendix B.

THE AMENDMENTS TO THE CLAIMS:

Claim 1 has been amended to recite that the solubilizer comprises a vitamin E substance and further that the fenofibrate is at least about 50% solubilized in the claimed composition. Support for the amendment can be found throughout the application as filed; for the "50% solubilized" recitation, see page 20, line 17.

Claim 50 has been amended to specify that the hydrophobic drug is one that has not been micronized, or that has been micronized in the absence of a solid surfactant. This amendment is supported in the specification on page 12, lines 22-28, on page 16, lines 7-10, and elsewhere.

Claim 51 has also been amended to clarify that the composition is to treat a patient suffering from a fenofibrate-responsive condition, disease or disorder. The new claim is supported by the specification on page 23, lines 19-22.

The remainder of the claim amendments do not materially affect the substance of the claims, and are entirely supported by the original disclosure.

The new claims are as follows.

New claim 52 specifies that the fenofibrate is completely solubilized in the composition, as disclosed in the specification on page 7, lines 5-6.

New claims 53, 61 and 86 specify the therapeutically effective amount of fenofibrate in the dosage form as a "unit dosage," which is supported on page 20, lines 11-12.

New claim 66 recites that the hydrophobic drug is selected from fenofibrate that has not been micronized and fenofibrate that has been micronized in the absence of a solid surfactant. This claim is supported in the specification on page 12, lines 22-28, on page 16, lines 7-10, and elsewhere.

New claims 91-94 recite fenofibrate-responsive conditions, diseases, or disorders as now specified in claim 51 as amended. The specific conditions, diseases and disorders recited in these new claims may be found in the specification on pages 9-10, bridging paragraph.

13

The remaining new claims parallel the originally filed claims, but depend from new independent claims 54 and 66. Accordingly, these new claims are fully supported by the original disclosure as well.

THE 35 U.S.C. §112, SECOND PARAGRAPH, REJECTION:

Claim 51 was rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicants regard as their invention. Specifically, the Examiner has taken the position that the phrase "treating a patient who would benefit from..." is vague and indefinite as allegedly not being clear as to scope. The Examiner questions whether applicants mean treating any condition, disease or disorder as described in the specification or whether applicants intend the treatment of specific lipid disorders.

While not wishing to acquiesce in the rejection, applicants have amended the claim to specify that the patient is suffering from a fenofibrate-responsive condition, disease or disorder, as explained in the specification on page 23, at lines 16-23. Applicants submit that as one of ordinary skill in the art, e.g., a physician or other medical professional, will recognize fenofibrate-responsive conditions, diseases and disorders, particularly when the claim is read in light of the disclosure in the patent application concerning such indications, the claim cannot be considered vague or indefinite. Reconsideration and withdrawal of the rejection under 35 U.S.C. §112, second paragraph, is respectfully requested.

THE 35 U.S.C. §102(B) REJECTION OVER EDGAR ET AL.:

The Examiner has rejected claims 1-4, 37, 41-44 and 51 as anticipated by Edgar et al., citing the reference as teaching a synergistic combination of 33-200 mg of fenofibrate and 100-600 mg of a vitamin E substance solution, in the form of a gelatin capsule, for treating and preventing pathological conditions including atheromatous disease, diabetes, arterial hypertension and restenosis. The Examiner also states that recitations of an inherent property of

a previously disclosed component, such as the solubilizing capability of a known vitamin E substance, does not limit composition claims.

It is axiomatic that in order to demonstrate anticipation, all elements of a claimed invention must be disclosed in a single prior art reference. *In re Bond*, 15 U.S.P.Q. 2d 1566, 1567 (Fed. Cir. 1990). Applicants respectfully submit that the reference does not disclose each and every element of the invention as recited in the pending claims, and therefore cannot anticipate the claimed invention.

With respect to those claims specifying that the fenofibrate is at least 50% solubilized in the composition (claims 1, 3, 4, 37-46, 50, 52, and 53), the Edgar et al. patent does not describe a composition of fenofibrate and a vitamin E substance as solubilizer wherein the fenofibrate is at least 50% solubilized.

That is:

(1) Edgar et al. discloses a ratio of fenofibrate to vitamin E substance having a lower limit of 0.33 mg fenofibrate to 1 IU of vitamin E substance, and an upper limit of 2 mg fenofibrate to 1 IU of vitamin E substance. The criticality of this ratio is repeated throughout the patent. See, for example: the abstract of the disclosure; column 3, lines 5-14; column 3, lines 26-28; column 4, lines 2-10; column 4, lines 25-30; column 5, lines 49-57; and the Examples. Edgar et al. does not disclose compositions containing fenofibrate and a vitamin E substance outside the 0.33 to 2 mg/IU range as the described ratio "is *always* between 0.33 and 2 mg/IU." See column 4, line 30 [emphasis added].

(2) Since 1 mg of d-α-tocopherol acetate = 1 IU (see column 1, line 55, of Edgar et al.), the Edgar et al. ratios are equivalent to a lower limit of 0.33 mg fenofibrate per 1 mg of d-α-tocopherol acetate up to an upper limit of 2 mg fenofibrate per 1 mg of d-α-tocopherol acetate.

(3) Then, since the solubility of fenofibrate in d-α-tocopherol acetate is 90-100 mg/g (i.e., 9 to 10 wt.%; see Example 6 of applicants' specification, on page 27), this means that only 0.09 mg to 0.10 mg fenofibrate is solubilized per IU of d-α-tocopherol acetate in the Edgar et al. compositions.

(4) This translates to 27.3% to 30.3% (0.09/0.33 to 0.10/0.33) of the fenofibrate being solubilized at the low end of the Edgar et al. ratio, and 4.5% to 5% (0.09/2 to 0.10/2) being solubilized at the upper end of the Edgar et al. ratio.

By contrast, in pending claims 1, 3, 4, 37-46, 50, 52, and 53, applicants are claiming a composition wherein a significantly higher percentage of fenofibrate is solubilized. Therefore, the Edgar et al. patent cannot anticipate those claims.

The remaining and new claims are also novel over Edgar et al., as the reference does not describe compositions containing fenofibrate and a solubilizer comprising a trialkyl citrate, a lactone, a nitrogen-containing solvent or a combination thereof (as required by independent claim 54 and all claims dependent thereon), nor are compositions disclosed wherein the fenofibrate is not micronized, or is micronized, but in the absence of a solid surfactant (as required by independent claim 66 and all claims dependent thereon). In fact, Edgar et al. requires that the fenofibrate be in the form of a micronized mixture of the drug and a solid surfactant (see, e.g., column 3, lines 17-18). With the compositions of applicants' claim 66-94, micronization is unnecessary.

Accordingly, reconsideration and withdrawal of the 35 U.S.C. §102(b) rejection over Edgar et al. is respectfully requested.

THE 35 U.S.C. §103(A) REJECTION OVER EDGAR ET AL. IN VIEW OF PATEL ET AL.:

The Examiner has additionally rejected claims 5-12, 38-40 and 45-50 under 35 U.S.C. §103(a) as obvious over Edgar et al. in view of Patel et al.

In response, applicants point out that the inventors on the Patel et al. patent are the same as the inventors on the present application, and that both applications are commonly owned and have always been subject to an obligation of common ownership. As a consequence, Patel et al. does not qualify as prior art under 35 U.S.C. §102(e) because the invention therein is not that "of another," nor can the patent be used in a rejection under 35 U.S.C. §103(a).

Applicants respectfully submit that the Edgar et al. reference alone does not support a rejection under 35 U.S.C. §103, insofar as there is no suggestion or motivation to modify the reference's teaching to substantially increase the amount of fenofibrate solubilized in the

B

disclosed compositions, or to forego co-micronization with a solid surfactant. Edgar et al. uses both fenofibrate and the vitamin E substance as antioxidants to protect plasma lipoproteins, particularly low density lipoproteins (LDLs), from oxidation. The ratio of fenofibrate to vitamin E substance, and the co-micronization of the fenofibrate with a solid surfactant, are stated as required to achieve the purpose of the invention, increasing the capability of both the vitamin E substance and the fenofibrate as antioxidants. See column 3, lines 5-13.

By contrast, applicants are providing a composition for administration of a fenofibrate as a pharmacologically active agent, wherein (a) absorption and thus the bioavailability of the drug are enhanced by providing a substantially greater fraction of the drug in solubilized form and/or (b) co-micronization of the fenofibrate with a solid surfactant is avoided. The claimed formulations in which the drug is not co-micronized with a solid surfactant are less costly to manufacture and commercialize than prior compositions (of which the Edgar et al. formulations are representative). Furthermore, the claimed formulations in which at least 50% of the fenofibrate is solubilized provide a significantly greater fraction of the drug in solubilized, absorbable form relative to prior compositions such as those disclosed by Edgar et al., meaning that the formulations are more easily administered (e.g., administered without regard to the timing of meals), thereby enhancing patient compliance as well.

Without *a priori* knowledge of applicants' invention, one would not be motivated to modify the Edgar et al. reference to arrive at applicants' claimed compositions. It is well settled in the law that such a "hindsight" analysis is improper in the context of an obviousness determination. Accordingly, a rejection under 35 U.S.C. §103 could not be maintained.

CONCLUSION

In sum, it is submitted that the claims satisfy the requirements of 35 U.S.C. §112 and define an invention that is patentable over the art. Accordingly, the application should now be in condition for allowance. A Notice of Allowance is requested, and a prompt mailing thereof would be much appreciated.

If the Examiner has any questions or wishes to discuss the matter further he may contact the undersigned at (650) 330-0900. Please note that this is a new telephone number, and that all future correspondence concerning this application should be directed to our new address, below.

Respectfully submitted,

10/24/01
Date

By: Dianne E Reed
Dianne E. Reed
Registration No. 31,292

REED & ASSOCIATES
800 Menlo Avenue, Suite 210
Menlo Park, California 94025
(650) 330-0900 Telephone
(650) 330-0980 Facsimile

13

APPENDIX A

REDACTED CLAIMS INDICATING AMENDMENTS MADE

IN THE CLAIMS:

Cancel claims 2, 13-36, 39 and 47-49 without prejudice.

Please amend claims 1, 3, 5, 8, 10, 37-43, 50 and 51 as follows:

1. (Amended) A pharmaceutical composition for oral administration of fenofibrate comprising:

a) a therapeutically effective amount of fenofibrate; and

b) a solubilizer comprising a vitamin E substance, ~~a trialkyl citrate, a lactone, a nitrogen-containing solvent or combination thereof~~

wherein the fenofibrate is at least about 50% solubilized in the composition.

3. (Amended) The pharmaceutical composition of claim ~~2~~ 1, wherein said vitamin E substance is selected from the group consisting of tocopherols, tocopherol derivatives with organic acids, tocotrienols and mixtures thereof.

5. (Amended) The pharmaceutical composition of claim ~~1~~ 54, wherein said solubilizer is a trialkyl citrate.

8. (Amended) The pharmaceutical composition of claim ~~1~~ 54, wherein said solubilizer is a lactone.

10. (Amended) The pharmaceutical composition of claim ~~1~~ 54, wherein said solubilizer is a nitrogen-containing solvent.

B

37. (Amended) The pharmaceutical composition of ~~any one of claims 1, 13, 15, 21, 24, 26, 31 or 36~~ claim 1, in a liquid form.

38. (Amended) The pharmaceutical composition of ~~any one of claims 1, 13, 15, 21, 24, 26, 31 or 36~~ claim 1, in a semi-liquid form.

40. (Amended) The pharmaceutical composition of ~~any one of claims 1, 13, 15, 21, 24, 26, 31 or 36~~ claim 1, wherein the fenofibrate is at least 75% solubilized in ~~said~~ the composition.

41. (Amended) A pharmaceutical dosage form comprising the pharmaceutical composition of ~~any one of claims 1, 13, 15, 21, 24, 26, 31 or 36~~ claim 1.

42. (Amended) The pharmaceutical dosage form of claim ~~41~~ 54, wherein the unit dosage of fenofibrate is ~~present in an amount of~~ from about 40 mg to about 250 mg.

43. (Amended) The pharmaceutical dosage form of claim ~~41~~ 54, wherein the unit dosage of fenofibrate is ~~present in an amount of~~ from about ~~40~~ 67 mg to about ~~250~~ 200 mg.

46. (Amended) The pharmaceutical composition of ~~any one of claims 1, 13, 15, 21, 24, 26, 31 or 36~~ claim 1, wherein the fenofibrate is completely solubilized in said composition.

50. (Amended) A pharmaceutical composition for administration of a hydrophobic drug comprising:

(a) a therapeutically effective amount of a hydrophobic drug; and

(b) a vitamin E substance,

wherein the hydrophobic drug is present in an amount of from about 0.1 to 30 % w/w of the composition and is at least about 50% solubilized in the composition, ~~and wherein~~ the vitamin E substance is present in an amount of from about 1 to 99 % w/w of said composition, and the hydrophobic drug is selected from the group consisting of hydrophobic drugs that have

B

not been micronized and hydrophobic drugs that have been micronized in the absence of a solid surfactant.

51. (Amended) A method for treating a patient ~~who would benefit from administration of a fenofibrate-containing composition~~ suffering from a fenofibrate-responsive condition, disease or disorder, comprising administering to the patient a therapeutically ~~acceptable~~ effective amount of the pharmaceutical composition of any one of claims 1, ~~13, 15, 21, 24, 26, 31 or 36~~54 or 66.

Also add the following new claims 52-94:

--52. The pharmaceutical composition of claim 40, wherein the fenofibrate is completely solubilized in the composition.

53. The pharmaceutical dosage form of claim 41, wherein the therapeutically effective amount of fenofibrate is a unit dosage.

54. A pharmaceutical composition for oral administration of fenofibrate, comprising:

a) a therapeutically effective amount of fenofibrate; and

b) an effective solubilizing amount of a solubilizer selected from the group consisting of a trialkyl citrate, a lactone, a nitrogen-containing solvent, and combinations thereof.

55. The pharmaceutical composition of claim 54, wherein the fenofibrate is at least 50% solubilized in the composition.

56. The pharmaceutical composition of claim 55, wherein the fenofibrate is at least 75% solubilized in the composition.

13

57. The pharmaceutical composition of claim 56, wherein the fenofibrate is completely solubilized in the composition.

58. The pharmaceutical composition of claim 54, in a liquid form.

59. The pharmaceutical composition of claim 54, in a semi-liquid form.

60. A pharmaceutical dosage form comprising the pharmaceutical composition of claim 54.

61. The pharmaceutical dosage form of claim 60, wherein the therapeutically effective amount of fenofibrate is a unit dosage.

62. The pharmaceutical dosage form of claim 60, wherein the unit dosage is from about 40 mg to about 250 mg.

63. The pharmaceutical dosage form of claim 62, wherein the unit dosage is from about 67 mg to about 200 mg.

64. The pharmaceutical dosage form of claim 60, in capsule form.

65. The pharmaceutical dosage form of claim 60, in the form of a drink.

66. A pharmaceutical composition for oral administration of fenofibrate comprising:

a) a therapeutically effective amount of a hydrophobic drug selected from the group consisting of fenofibrate that has not been micronized and fenofibrate that has been micronized in the absence of a solid surfactant; and

b) a solubilizer comprising a vitamin E substance, a trialkyl citrate, a lactone, a nitrogen-containing solvent or combination thereof; and

c) an optional solid surfactant.

67. The pharmaceutical composition of claim 66, wherein the fenofibrate has not been micronized.

68. The pharmaceutical composition of claim 66, wherein the fenofibrate has been micronized in the absence of a solid surfactant.

69. The pharmaceutical composition of claim 66, wherein the solubilizer is a vitamin E substance.

70. The pharmaceutical composition of claim 69, wherein the vitamin E substance is selected from the group consisting of tocopherols, tocopherol derivatives with organic acids, tocotrienols and mixtures thereof.

71. The pharmaceutical composition of claim 70, wherein the vitamin E substance is selected from the group consisting of alpha tocopherol, alpha tocopheryl acetate, alpha tocopheryl acid succinate, alpha tocopherol polyethylene glycol 1000 succinate and mixtures thereof.

72. The pharmaceutical composition of claim 71, wherein the solubilizer is a trialkyl citrate.

73. The pharmaceutical composition of claim 72, wherein the trialkyl citrate is selected from the group consisting of triethyl citrate, acetyltriethyl citrate, tributyl citrate, acetyltributyl citrate and mixtures thereof.

74. The pharmaceutical composition of claim 73, wherein the trialkyl citrate is triethyl citrate.

13

75. The pharmaceutical composition of claim 66, wherein the solubilizer is a lactone.

76. The pharmaceutical composition of claim 75, wherein the lactone is selected from the group consisting of ε-caprolactone and isomers thereof, δ-valerolactone and isomers thereof and β-butyrolactone and isomers thereof and mixtures thereof.

77. The pharmaceutical composition of claim 66, wherein the solubilizer is a nitrogen-containing solvent.

78. The pharmaceutical composition of claim 77, wherein said nitrogen-containing solvent is selected from the group consisting of dimethylformamide, dimethylacetamide, N-alkylpyrrolidone, N-hydroxyalkylpyrrolidone, N-alkylpiperidone, N-alkylcaprolactam and mixtures thereof.

79. The pharmaceutical composition of claim 78, wherein the solubilizer is selected from the group consisting of N-methyl 2-pyrrolidone, N-ethyl 2-pyrrolidone and mixtures thereof.

80. The pharmaceutical composition of claim 66, in a liquid form.

81. The pharmaceutical composition of claim 66, in a semi-liquid form.

82. The pharmaceutical composition of claim 66, wherein the fenofibrate is at least 50% solubilized in the composition.

83. The pharmaceutical composition of claim 82, wherein the fenofibrate is at least 75% solubilized in the composition.

84. The pharmaceutical composition of claim 83, wherein the fenofibrate is completely solubilized in the composition.

85. A pharmaceutical dosage form comprising the pharmaceutical composition of claim 66.

86. The pharmaceutical dosage form of claim 85, wherein the therapeutically effective amount of fenofibrate is a unit dosage.

87. The pharmaceutical dosage form of claim 86, wherein the unit dosage of fenofibrate is from about 40 mg to about 250 mg.

88. The pharmaceutical dosage form of claim 87, wherein the unit dosage of fenofibrate is from about 67 mg to about 200 mg.

89. The pharmaceutical dosage form of claim 85, in capsule form.

90. The pharmaceutical dosage form of claim 85, in the form of a drink.

91. The method of claim 51, wherein the fenofibrate-responsive condition, disease or disorder is a lipid disorder.

92. The method of claim 91, wherein the lipid disorder is an above-normal level of cholesterol.

93. The method of claim 91, wherein the lipid disorder is an above-normal triglyceride level.

94. The method of claim 91, wherein the lipid disorder is a below-normal level of high density lipoproteins.--

APPENDIX B

PENDING CLAIMS UPON ENTRY OF THE AMENDMENTS

1. A pharmaceutical composition for oral administration of fenofibrate comprising:

a) a therapeutically effective amount of fenofibrate; and 40-350-F

b) a solubilizer comprising a vitamin E substance,

wherein the fenofibrate is at least about 50% solubilized in the composition.

3. The pharmaceutical composition of claim 1, wherein said vitamin E substance is selected from the group consisting of tocopherols, tocopherol derivatives with organic acids, tocotrienols and mixtures thereof.

4. The pharmaceutical composition of claim 3, wherein said vitamin E substance is selected from the group consisting of alpha tocopherol, alpha tocopheryl acetate, alpha tocopheryl acid succinate, alpha tocopherol polyethylene glycol 1000 succinate and mixtures thereof.

5. The pharmaceutical composition of claim 54, wherein said solubilizer is a trialkyl citrate.

6. The pharmaceutical composition of claim 5, wherein said trialkyl citrate is selected from the group consisting of triethyl citrate, acetyltriethyl citrate, tributyl citrate, acetyltributyl citrate and mixtures thereof.

7. The pharmaceutical composition of claim 6, wherein said trialkyl citrate is triethyl citrate.

8. The pharmaceutical composition of claim 54, wherein said solubilizer is a lactone.

9. The pharmaceutical composition of claim 8, wherein said lactone is selected from the group consisting of ε-caprolactone and isomers thereof, δ-valerolactone and isomers thereof and β-butyrolactone and isomers thereof and mixtures thereof.

10. The pharmaceutical composition of claim 54, wherein said solubilizer is a nitrogen-containing solvent.

11. The pharmaceutical composition of claim 10, wherein said nitrogen-containing solvent is selected from the group consisting of dimethylformamide, dimethylacetamide, N-alkylpyrrolidone, N-hydroxyalkylpyrrolidone, N-alkylpiperidone, N-alkylcaprolactam and mixtures thereof.

12. The pharmaceutical composition of claim 10, wherein said solubilizer is selected from the group consisting of N-methyl 2-pyrrolidone, N-ethyl 2-pyrrolidone and mixtures thereof.

37. The pharmaceutical composition of claim 1, in a liquid form.

38. The pharmaceutical composition of claim 1, in a semi-liquid form.

40. The pharmaceutical composition of claim 39, wherein the fenofibrate is at least 75% solubilized in said composition.

41. A pharmaceutical dosage form comprising the pharmaceutical composition of claim 1.

42. The pharmaceutical dosage form of claim 54, wherein the unit dosage of fenofibrate is from about 40 mg to about 250 mg.

43. The pharmaceutical dosage form of claim 54, wherein the unit dosage of fenofibrate is from about 67 mg to about 200 mg.

44. The pharmaceutical dosage form of claim 41, in capsule form.

45. The pharmaceutical dosage form of claim 41, in the form of a drink.

46. The pharmaceutical composition of claim 1, wherein the fenofibrate is completely solubilized in said composition.

50. A pharmaceutical composition for administration of a hydrophobic drug comprising:

(a) a therapeutically effective amount of a hydrophobic drug; and

(b) a vitamin E substance,

wherein the hydrophobic drug is present in an amount of from about 0.1 to 30 % w/w of the composition and is at least about 50% solubilized in the composition, the vitamin E substance is present in an amount of from about 1 to 99 % w/w of said composition, and the hydrophobic drug is selected from the group consisting of hydrophobic drugs that have not been micronized and hydrophobic drugs that have been micronized in the absence of a solid surfactant.

51. A method for treating a patient suffering from a fenofibrate-responsive condition, disease or disorder, comprising administering to the patient a therapeutically effective amount of any one of claims 1, 54 or 66.

52. The pharmaceutical composition of claim 40, wherein the fenofibrate is completely solubilized in the composition.

53. The pharmaceutical dosage form of claim 41, wherein the therapeutically effective amount of fenofibrate is a unit dosage.

54. A pharmaceutical composition for oral administration of fenofibrate, comprising:

a) a therapeutically effective amount of fenofibrate; and

b) an effective solubilizing amount of a solubilizer selected from the group consisting of a trialkyl citrate, a lactone, ~~a nitrogen-containing solvent~~, and combinations thereof.

55. The pharmaceutical composition of claim 54, wherein the fenofibrate is at least 50% solubilized in the composition.

56. The pharmaceutical composition of claim 55, wherein the fenofibrate is at least 75% solubilized in the composition.

57. The pharmaceutical composition of claim 56, wherein the fenofibrate is completely solubilized in the composition.

58. The pharmaceutical composition of claim 54, in a liquid form.

59. The pharmaceutical composition of claim 54, in a semi-liquid form.

60. A pharmaceutical dosage form comprising the pharmaceutical composition of claim 54.

61. The pharmaceutical dosage form of claim 60, wherein the therapeutically effective amount of fenofibrate is a unit dosage.

62. The pharmaceutical dosage form of claim 60, wherein the unit dosage is from about 40 mg to about 250 mg.

63. The pharmaceutical dosage form of claim 62, wherein the unit dosage is from about 67 mg to about 200 mg.

64. The pharmaceutical dosage form of claim 60, in capsule form.

65. The pharmaceutical dosage form of claim 60, in the form of a drink.

66. A pharmaceutical composition for oral administration of fenofibrate comprising:

a) a therapeutically effective amount of a hydrophobic drug selected from the group consisting of fenofibrate that has not been micronized and fenofibrate that has been micronized in the absence of a solid surfactant; and

b) a solubilizer comprising a vitamin E substance, a trialkyl citrate, a lactone, a nitrogen-containing solvent or combination thereof; and

c) an optional solid surfactant.

67. The pharmaceutical composition of claim 66, wherein the fenofibrate has not been micronized.

68. The pharmaceutical composition of claim 66, wherein the fenofibrate has been micronized in the absence of a solid surfactant.

69. The pharmaceutical composition of claim 66, wherein the solubilizer is a vitamin E substance.

70. The pharmaceutical composition of claim 69, wherein the vitamin E substance is selected from the group consisting of tocopherols, tocopherol derivatives with organic acids, tocotrienols and mixtures thereof.

71. The pharmaceutical composition of claim 70, wherein the vitamin E substance is selected from the group consisting of alpha tocopherol, alpha tocopheryl acetate, alpha tocopheryl acid succinate, alpha tocopherol polyethylene glycol 1000 succinate and mixtures thereof.

72. The pharmaceutical composition of claim 71, wherein the solubilizer is a trialkyl citrate.

73. The pharmaceutical composition of claim 72, wherein the trialkyl citrate is selected from the group consisting of triethyl citrate, acetyltriethyl citrate, tributyl citrate, acetyltributyl citrate and mixtures thereof.

74. The pharmaceutical composition of claim 73, wherein the trialkyl citrate is triethyl citrate.

75. The pharmaceutical composition of claim 66, wherein the solubilizer is a lactone.

76. The pharmaceutical composition of claim 75, wherein the lactone is selected from the group consisting of ε-caprolactone and isomers thereof, δ-valerolactone and isomers thereof and β-butyrolactone and isomers thereof and mixtures thereof.

77. The pharmaceutical composition of claim 66, wherein the solubilizer is a nitrogen-containing solvent.

78. The pharmaceutical composition of claim 77, wherein said nitrogen-containing solvent is selected from the group consisting of dimethylformamide, dimethylacetamide, N-alkylpyrrolidone, N-hydroxyalkylpyrrolidone, N-alkylpiperidone, N-alkylcaprolactam and mixtures thereof.

79. The pharmaceutical composition of claim 78, wherein the solubilizer is selected from the group consisting of N-methyl 2-pyrrolidone, N-ethyl 2-pyrrolidone and mixtures thereof.

80. The pharmaceutical composition of claim 66, in a liquid form.

81. The pharmaceutical composition of claim 66, in a semi-liquid form.

82. The pharmaceutical composition of claim 66, wherein the fenofibrate is at least 50% solubilized in the composition.

83. The pharmaceutical composition of claim 82, wherein the fenofibrate is at least 75% solubilized in the composition.

84. The pharmaceutical composition of claim 83, wherein the fenofibrate is completely solubilized in the composition.

85. A pharmaceutical dosage form comprising the pharmaceutical composition of claim 66.

86. The pharmaceutical dosage form of claim 85, wherein the therapeutically effective amount of fenofibrate is a unit dosage.

87. The pharmaceutical dosage form of claim 86, wherein the unit dosage of fenofibrate is from about 40 mg to about 250 mg.

88. The pharmaceutical dosage form of claim 87, wherein the unit dosage of fenofibrate is from about 67 mg to about 200 mg.

89. The pharmaceutical dosage form of claim 85, in capsule form.

90. The pharmaceutical dosage form of claim 85, in the form of a drink.

91. The method of claim 51, wherein the fenofibrate-responsive condition, disease or disorder is a lipid disorder.

92. The method of claim 91, wherein the lipid disorder is an above-normal level of cholesterol.

93. The method of claim 91, wherein the lipid disorder is an above-normal triglyceride level.

94. The method of claim 91, wherein the lipid disorder is a below-normal level of high density lipoproteins.